

App. Control No. 09/843,914  
Art Unit: 3762

**REMARKS**

The final Office Action addressed pending claims 1 and 20, rejecting both. Herein Applicant amends claims 1 and 20 and adds new claims 37 – 49, including new independent claim 45 directed to a computer readable medium storing executable instructions for operating a medical device to perform the inventive method recited in claim 1 (and claims 37-41 depending therefrom).

The present Amendment After Final is intended to place the application in condition for allowance without requiring additional search or raising additional issues for the Examiner to address. The present amendment was not earlier tendered because the Applicant sincerely believed that the two pending claims of the application were already in condition for allowance having successfully traversed the obviousness rejection founded on Alt and Bardy. Applicant herein amends the two pending independent claims to (again) distinguish over Alt and Bardy in that neither Alt nor Bardy provides a different tachycardia response therapy depending upon whether a detected tachycardia event is hemodynamically stable or not.

Entry and favorable consideration of the pending claims is earnestly solicited so that the claimed invention may pass to timely issuance as U.S. Letters Patent.

**Claims Rejections Under 35 U.S.C. §103**

Claim 1 and 20 stand rejected as being unpatentable over U.S. Pat. No. 5,458,622 to Alt (Alt) in view of U.S. Pat. No. 5,257,621 to Bardy et al. (Bardy).

After studying the combination posed by the Examiner, Applicant respectfully suggests that the Examiner repeatedly attempts to extend Alt from its primary if not exclusive focus of what is termed a complementary sensor. The complementary sensor

App. Control No. 09/843,914

Art Unit: 3762

of Alt is based exclusively on "activity" (as sensed by an accelerometer) and Alt only notes that an "indirect activity sensor" may also be used. Without explanation, however, the Examiner unilaterally shortened the phrase "indirect activity sensor" to "*indirect sensor.*" The Examiner cites the same *modified* passage from Alt *three times*. However, as clearly set forth in Alt such a complementary sensor is actually "an indirect sensor of physical exercise of a patient such as blood pressure" (col. 3, ll. 24-25 – emphasis added). Applicant suggests that the Examiner has unfairly modified or characterized Alt although Alt is devoid of any disclosure, depiction or enablement regarding lowering tachycardia detection criteria based solely on heart rate and blood pressure measurements of a patient. Moreover, Alt is devoid of any teaching regarding what type of blood pressure sensor should be chronically deployed into fluid communication with a patient, how a direct pressure signal might relate to a physiologic normal sinus tachycardia versus a pathological tachycardia. That is, assuming *arguendo* that Alt contained some suggestion motivating one of skill in the art to combine heart rate, activity and blood pressure metrics into an ICD Alt is essentially inoperable.

Since according to the foregoing the Examiner has failed to meet the burden of establishing that Alt is a credible reference and thus that the asserted combination of Alt and Bardy is inherently flawed (i.e., does not constitute a *prima facie* obviousness rejection), Applicant respectfully requests that said rejection be withdrawn.

With respect to Bardy, a defibrillator having an arrhythmia detection capability to distinguish high rate monomorphic ventricular tachycardia from ventricular fibrillation. Bardy teaches to activate the tachycardia/fibrillation discrimination function upon

App. Control No. 09/843,914  
Art Unit: 3762

detection of a high heart rate. The discrimination function operates to determine the beat-to-beat variability of the measured heart rate intervals. Fibrillation is determined to exist if the beat-to-beat variability over a physician-programmable predetermined number of intervals exceeds a predetermined variability threshold.

In summary, Alt teaches to use patient physical activity level to determine whether a high heart rate is pathologic or physiologic (i.e., whether it is due to pathologic tachycardia or a response to physical exertion). Bardy teaches to discriminate between high rate tachycardia and fibrillation on the basis of beat-to-beat variability after a high heart rate has been detected. Neither reference appears to distinguish between hemodynamically stable and unstable tachycardia episodes and respond with a different therapy depending upon such a distinguishing characteristic.

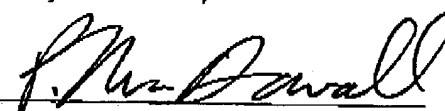
The Examiner attempts to combine the references (without any providing any showing of the desirability, motivation or suggestion for such a combination from either Alt or Bardy) and concludes that the claimed subject matter of the present invention is obvious. Applicant contends that both Alt and Bardy are devoid of any teaching or disclosure regarding use of only direct hemodynamic measurements and heart rate measurements to distinguish between tachycardia episodes and to respond depending on the stability of said hemodynamic measurements. Furthermore, both Alt and Bardy are devoid of any appropriate blood pressure sensors, signal handling, and any direct relationships between heart rate, blood pressure and tachycardia status.

App. Control No. 09/843,914  
Art Unit: 3762

Applicant submits that all pending claims are in condition for allowance and requests that a notice of allowance should be issued in due course.

Date: 30 August 2004

Respectfully submitted,

By: 

Paul H. McDowall  
Reg. No. 34,873  
Telephone: (763) 514-3351  
Customer 27581